DISPERSE BLUE 1 CAS No. 2475-45-8

First Listed in the Eighth Report on Carcinogens

CARCINOGENICITY

Disperse Blue 1 is *reasonably anticipated to be a human carcinogen* based on evidence of malignant tumor formation in experimental animals to an unusual degree with regard to incidence, site and type of tumor (NTP 299, 1986), and because it is a member of a well-defined, structurally related class of substances listed in a previous Annual Report on Carcinogens as either known to be human carcinogens or reasonably anticipated to be human carcinogens (NTP, 1994).

Disperse Blue 1 was a carcinogen in both sexes of F344/N rats; the findings in B6C3F₁ mice were equivocal. Clear evidence of carcinogenicity in the urinary bladder of F344/N rats was evidenced by increased incidences of transitional cell neoplasms, leiomyomas or leiomyosarcomas, and squamous cell neoplasms (NTP 299, 1986). Transitional cell and squamous cell tumors of the urinary bladder of male F344 rats receiving Disperse Blue 1 were also noted in a small study reported by Burnett and Squire (1986).

ADDITIONAL INFORMATION RELEVANT TO CARCINOGENESIS OR POSSIBLE MECHANISMS OF CARCINOGENESIS

Neoplasms in the urinary bladder of rats were associated with dose-dependent incidences of calculi that were thought to induce chronic inflammation and cell proliferation. Calculi and resulting inflammatory and proliferative lesions also occurred in the urinary bladders of both sexes of B6C3F₁ mice in the absence of significantly increased incidences of neoplastic lesions (NTP 299, 1986).

Data on the genotoxicity of Disperse Blue 1 indicate that it induced a weak positive response in *Salmonella* (Brown and Brown, 1976; cited by IARC V.48, 1990), DNA damage (SCE) and chromosomal aberrations in CHO cells (Anderson et al., 1990), *tk* gene mutations in mouse lymphoma L5178Y cells (Myhr et al., 1990; cited by Cosmetic Ingredient Review Board, 1995), and morphological transformation in Balb/c 3T3 mouse cells (Matthews et al., 1993). NTP studies of structurally related compounds, nitro- and aminoanthraquinones, have demonstrated that each compound tested has some activity as a mutagen. Most compounds of this class that have been the subjects of two-year studies have also been found to be carcinogenic in one or more species. Sites of tumor development include the urinary bladder in rats and the liver of both rats and mice.

Data are available to suggest that transitional cell and squamous cell tumors induced by Disperse Blue 1 in the urinary bladder would not occur in humans exposed to amounts of

Disperse Blue 1 insufficient to also cause bladder calculi. However, compelling data which demonstrate a causal relationship between urinary bladder calculi and leiomyomas and leiomyosarcomas have not been sufficiently developed to establish that Disperse Blue 1 would not be *reasonably anticipated to be a human carcinogen*.

PROPERTIES

Disperse Blue 1 is a blue-black microcrystalline powder containing approximately 50% 1,4,5,8-tetraaminoanthraquinone, 30% other compounds structurally related to 1,4,5,8-tetraaminoanthraquinone, and 20% water. It is soluble in acetone, ethanol, and Cellosolve; slightly soluble in benzene and linseed oil; and very slightly soluble in water. Disperse Blue 1 melts at 332 °C and degrades at greater than -20 °C. When heated to decomposition, Disperse Blue 1 emits toxic fumes of nitrogen oxides (NO_x) (IARC V.48, 1990).

USE

Disperse Blue 1 is not known to occur as a natural product but is produced and used as a mixture of chemicals. It is an aminoanthraquinone-based dyestuff used in hair color formulations and in coloring fabrics and plastics. Commercial preparations of Disperse Blue 1 contain approximately equal amounts of dyestuff and lignosulfonate dispersants. Over 3 million people in the United States use hair color preparations containing Disperse Blue 1 in semipermanent hair color formulations at concentrations of less than 1%. Disperse Blue 1 has been used as a fabric dye for nylon, cellulose acetate and triacetate, polyester, and acrylate fibers. It has also been used for surface dyeing of thermoplastics and as a solvent dye in cellulose acetate plastics (NTP 299, 1986; IARC V.48, 1990). Disperse Blue 1 is also used to dye fur, solvents, resins, and lacquers (Green, 1990; cited by Haws et al., 1994).

PRODUCTION

Disperse Blue 1 is no longer used in the United States (NTP 299, 1986). Chem Sources (1996) identified three U.S. suppliers of the compound in 1996. The USITC listed one manufacturer of the chemical for 1993 and 1994 (USITC, 1994, 1995). For all previous years, the total production volume of all Disperse Blue dyes was reported (USITC, 1984-1991, 1993). The last reported value was over 350,500 lb in 1972. After 1972, separate figures were no longer disclosed (IARC V.48, 1990). The United States imported approximately 7700 lb of Disperse Blue 1 in 1980, 8800 lb in 1981, 8085 lb in 1982, and 13,756 lb in 1983 (USITCa, 1980-1983).

EXPOSURE

The primary routes of potential human exposure to Disperse Blue 1 are inhalation and dermal contact. Since Disperse Blue 1 is used in hair dyes, potential exposure by these routes exists for personnel producing and applying such products (IARC V.48, 1990), as well as for those subjected to their administration. In the mid 1980s, it was reported that over 3 million people in the United States used semipermanent hair color preparations containing Disperse Blue 1 at concentrations of less than 1% (NTP 299, 1986). The National Occupational Hazard Survey, conducted by NIOSH from 1972 to 1974, estimated that 482 workers were potentially exposed to Disperse Blue 1 in the workplace (NIOSH, 1976). The National Occupational Exposure Survey (1981-1983) indicated that 43,522 workers, including 32,059 women, were potentially exposed to Disperse Blue 1 (NIOSH, 1990).

REGULATIONS

OSHA regulates Disperse Blue 1 under the Hazard Communication Standard and as a chemical hazard in laboratories. There is no OSHA Permissible Exposure Limit (PEL) and no ACGIH or NIOSH workroom air exposure criteria.

EPA regulates Disperse Blue 1 under SARA 312 as an extremely hazardous substance and under TSCA. Disperse Blue 1 was listed on the EPA TSCA Chemical Inventory List (1992) (CHEMTOX, 1996).

An October 1996 search of the Federal Register (1988-1996) fulltext and Federal Register Abstracts (1977-1993) found no mention of Disperse Blue 1 except for the 1986 announcement of availability of the NTP bioassay report (NTP 299, 1986). Regulations are summarized in Volume II, Table B-57.